agree to establish and follow security precautions considered by the Food and Drug Administration to be necessary to ensure proper and confidential handling of the data and information. The written agreement shall include, where appropriate, provisions establishing:

(1) Restrictions on access to the data and information by the contractor, its employees, or other persons;

(2) Physical storage requirements;

(3) Requirements for the handling and accountability of the data and information by the contractor and its employees;

(4) Limitations on reproduction, transmission, and disclosure of the data and information;

(5) A requirement of advance approval by the Food and Drug Administration of the use by the contractor of subcontractors, vendors, or suppliers;

(6) Procedures to be followed when the contractor employs time-shared computer operations;

(7) Methods of destroying source documents or related waste material; and

(8) The period during which the contractor may retain such data and information.

§ 20.91 Use of data or information for administrative or court enforcement action.

Nothing in this part or this chapter shall prevent the Food and Drug Administration from using any data or information, whether obtained voluntarily or involuntarily and whether or not it is available for public disclosure, as the basis for taking any administrative or court enforcement action within its jurisdiction. Data and information otherwise exempt from public disclosure are nevertheless available for public disclosure to the extent necessary to effectuate such action, e.g., the brand name, code designation, and distribution information are released when a product is recalled.

Subpart F—Availability of Specific Categories of Records

§ 20.100 Applicability; cross–reference to other regulations.

(a) The provisions set forth in this subpart or cross-referenced in paragraph (c) of this section state the way in which specific categories of Food and Drug Administration records are handled upon a request for public disclosure. The exemptions established in subpart D of this part and the limitations on exemptions established in subpart E of this part shall be applicable to all Food and Drug Administration records, as provided in §§ 20.60 and 20.80. Accordingly, a record that is ordinarily available for public disclosure in accordance with this part or under other regulations is not available for such disclosure to the extent that it falls within an exemption contained in subpart D of this part except as provided by the limitations on exemptions specified in subpart E of this part.

(b) The Commissioner, on his own initiative or on the petition of any interested person, may amend this subpart or promulgate and cross-reference additional regulations to state the status of additional categories of documents to settle pending questions or to reflect court decisions.

(c) In addition to the provisions of this part, rules on the availability of the following specific categories of Food and Drug Administration records are established by regulations in this chapter:

(1) Section 305 hearing records, in § 7.87(c) of this chapter.

(2) Flavor ingredient records and notes, in § 101.22(i)(4)(iv) of this chapter.

(3) Environmental assessments; finding of no significant impact, in § 25.51 of this chapter, or draft and final environmental impact statements, in § 25.52 of this chapter.

(4) Color additive petitions, in § 71.15 of this chapter.

(5) Food standard temporary permits, in § 130.17(k) of this chapter.

(6) Information on thermal processing of low-acid foods packaged in hermetically sealed containers, in § 108.35(l) of this chapter.

(7) Food additive petitions, in §§ 171.1(h) and 571.1(h) of this chapter.

(8) Action levels for natural and unavoidable defects in food for human use, in § 110.110(e) of this chapter.

(9) Drug establishment registrations and drug listings, in § 207.37 of this chapter.

(10) Investigational new animal drug notices, in § 514.12 of this chapter.

(11) New animal drug application files, in § 514.11 of this chapter.

(12) Investigational new animal drug notice and a new animal drug application file for an antibiotic drug, in § 514.10 of this chapter.

(13) Methadone patient records, in § 291.505(g) of this chapter.

(14) Investigational new drug notice, in § 312.130 of this chapter.

(15) Labeling for and lists of approved new drug applications, in § 314.430 of this chapter.

(16) Master file for a new drug application, in § 312.420 of this chapter.

(17) New drug application file, in § 314.430 of this chapter.

(18) Data and information submitted for in vitro diagnostic products, in § 809.4 of this chapter.

(19) Data and information submitted for OTC drug review, in § 330.10(a)(2) of this chapter.

(20) Investigational new drug notice for an antibiotic drug, in § 431.70 of this chapter.

(21) Antibiotic drug file, in § 314.430 of this chapter.

(22) Data and information submitted for biologics review, in § 601.25(b)(2) of this chapter.

(23) Investigational new drug notice for a biological product, in § 601.50 of this chapter.

(24) Applications for biologics licenses for biological products, in § 601.51 of this chapter.

(25) Cosmetic establishment registrations, in § 710.7 of this chapter.

(26) Cosmetic product ingredient and cosmetic raw material composition statements, § 720.8 of this chapter.

(27) Cosmetic product experience reports, in § 730.7 of this chapter.

(28) Device premarket notification submissions, in § 807.95 of this chapter.

(29) Electronic product information, in §§ 1002.4 and 1002.42 of this chapter.

(30) Data and information submitted to the Commissioner or to classification panels in connection with the classification or reclassification of devices intended for human use, in § 860.5 of this chapter.

(31) Data and information submitted in offers to develop a proposed performance standard for medical devices, in § 861.26 of this chapter.

(32) Investigational device exemptions in § 812.38 of this chapter.

(33) Health claims petitions, in § 101.70 of this chapter.

(34) Premarket approval application, in § 814.9 of this chapter.

(35) Report of certain adverse experiences with a medical device, in § 803.9 of this chapter.

(36) Disqualification determination of an institutional review board, in § 56.122 of this chapter.

(37) Disqualification determination of a nonclinical laboratory, in § 58.213 of this chapter.

(38) Minutes or records regarding a public advisory committee, in § 14.65(c) of this chapter.

(39) Data submitted regarding persons receiving an implanted pacemaker device or lead, in § 805.25 of this chapter.

(40) Humanitarian device exemption application, in § 814.122 of this chapter.

[42 FR 15616, Mar. 22, 1977, as amended at 42 FR 19989, Apr. 15, 1977; 42 FR 42526, Aug. 28, 1977; 42 FR 58889, Nov. 11, 1977; 43 FR 32993, July 28, 1978; 51 FR 22475, June 19, 1986; 54 FR 9038, Mar. 3, 1989; 58 FR 2533, Jan. 6, 1993; 59 FR 536, Jan. 5, 1994; 61 FR 33244, June 26, 1996; 62 FR 40592, July 29, 1997; 64 FR 56448, Oct. 20, 1999; 67 FR 13717, Mar. 26, 2002]

§ 20.101 Administrative enforcement records.

(a) All Food and Drug Administration records relating to administrative enforcement action disclosed to any member of the public, including the person who is the subject of such action, are available for public disclosure at the time such disclosure is first made. Such records include correspondence with companies following factory inspection, recall or detention requests, notice of refusal of admission of an imported product, regulatory letters, information letters, Forms FD–483 and FD–2275 furnished to companies after factory inspection, and similar records.

(b) To the extent that any of such records fall within the exemption for investigatory records established in § 20.64, the Commissioner determines that they are subject to discretionary release pursuant to § 20.82.